

AMENDMENTS TO THE CLAIMS

A complete list of claims as currently amended follows:

1. (currently amended) A pharmaceutical dosage form having a first and second active drug, said dosage form comprising:
 - (a) a controlled release core ~~consists~~ consisting essentially of metfomin or a pharmaceutically acceptable salt thereof a biguanide drug and at least one pharmaceutically acceptable excipient.
 - (b) a primary seal coat that does not contain an active pharmaceutical ingredient, that rapidly disperses or dissolves in water and that is applied to the controlled release core; and
 - (c) an immediate release thiazolidinedione derivative containing ~~coating~~ coat applied to the primary seal coating coat wherein the thiazolidinedione derivative is troglitazone, rosiglitazone, pioglitazone, ciglitazone or pharmaceutically acceptable salts, isomers or derivatives thereof.
2. (original) The dosage form of claim 1 wherein said controlled release core is an osmotic tablet.
3. (currently amended) The dosage form of claim 2 wherein the osmotic tablet consists essentially of:
 - (a) a core consisting essentially of:
 - (i) 50-98% of said biguanide drug metformin or a pharmaceutically acceptable salt thereof;
 - (ii) 0.1-40% of a binding agent;
 - (iii) 0-20% of an absorption enhancer; and
 - (iv) 0-5% of a lubricant;
 - (b) optionally a secondary seal coat surrounding the core; and
 - (c) a semipermeable membrane consisting essentially of:
 - (i) 50-99% of a polymer;
 - (ii) 0-40% of a flux enhancer and

- (iii) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the ~~biguanide drug~~ metformin or a pharmaceutically acceptable salt thereof.
4. (currently amended) The dosage form of claim 1 wherein said metformin or a pharmaceutically acceptable salt thereof ~~biguanide~~ is metformin hydrochloride and the thiazolidinedione derivative is pioglitazone hydrochloride.
5. (canceled).
6. (canceled).
7. (currently amended) The dosage form of claim 1 wherein the release of the ~~biguanide drug~~ metformin or a pharmaceutically acceptable salt thereof is not regulated by an expanding polymer.
8. (currently amended) The dosage form of claim 1 wherein said controlled release of said ~~biguanide drug~~ metformin or a pharmaceutically acceptable salt thereof provides a Tmax of 8-12 hours.
9. (original) The dosage form of claim 1 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-12 hours.
10. (original) The dosage form of claim 9 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-4 hours.
11. (currently amended) A pharmaceutical dosage form having a first and second active drug, said dosage form comprising:
- a controlled release core consisting essentially of a ~~biguanide drug~~ metformin or a pharmaceutically acceptable salt thereof and at least one pharmaceutically acceptable excipient;
 - a primary seal coat that does not contain an active pharmaceutical ingredient, that rapidly disperses or dissolves in water and that is applied to the controlled release core; and
 - an immediate release thiazolidinedione derivative containing coating coat applied to the primary seal coating coat comprising:
 - a thiazolidinedione derivative; and
 - a binder;

wherein the immediate release ~~coating coat~~ is applied to the primary seal coating coat using a solvent mixture comprising water and an organic solvent and wherein the thiazolidinedione derivative is troglitazone, rosiglitazone, pioglitazone, ciglitazone or pharmaceutically acceptable salts, isomers or derivatives thereof.

12. (original) The dosage form of claim 11 wherein said controlled release core is an osmotic tablet.
13. (currently amended) The dosage form of claim 12 wherein the osmotic tablet consists essentially of:
 - (a) a core consisting essentially of:
 - (i) 50-98% of said ~~biguanide drug~~ metformin or a pharmaceutically acceptable salt thereof;
 - (ii) 0.1-40% of a binding agent;
 - (iii) 0-20% of an absorption enhancer; and
 - (iv) 0-5% of a lubricant;
 - (b) optionally a secondary seal coat surrounding the core; and
 - (c) a semipermeable membrane consisting essentially of:
 - (i) 50-99% of a polymer;
 - (ii) 0-40% of a flux enhancer; and
 - (iii) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the metformin or a pharmaceutically acceptable salt thereof biguanide drug.
14. (currently amended) The dosage form of claim 11 wherein said metformin or a pharmaceutically acceptable salt thereof biguanide is metformin hydrochloride and the thiazolidinedione derivative is pioglitazone hydrochloride.
15. (canceled).
16. (canceled).
17. (currently amended). The dosage form of claim 11 wherein the release of the ~~biguanide drug~~ metformin or a pharmaceutically acceptable salt thereof is not regulated by an expanding polymer.

18. (currently amended) The dosage form of claim 11 wherein said controlled release of said ~~biguanide drug~~ metformin or a pharmaceutically acceptable salt thereof provides a Tmax of 8-12 hours.
19. (original) The dosage form of claim 11 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-12 hours.
20. (original) The dosage form of claim 19 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-4 hours.
21. (currently amended) A pharmaceutical dosage form having a first and second active drug, said dosage form comprising:
- (a) a controlled release core consisting essentially of ~~a biguanide drug~~ metformin or a pharmaceutically acceptable salt thereof and at least one pharmaceutically acceptable excipient;
 - (b) a primary seal coat that does not contain an active pharmaceutical ingredient, that rapidly disperses or dissolves in water and that is applied to the controlled release core; and
 - (c) an immediate release thiazolidinedione derivative containing coating coat applied to the primary seal coat comprising:
 - (i) a thiazolidinedione derivative;
 - (ii) a binder;
 - (iii) a surfactant; and
 - (iv) a pore former;

wherein the immediate release coating coat is applied to the primary seal coat using water, an organic solvent or a solvent mixture comprising water and an organic solvent and wherein the thiazolidinedione derivative is troglitazone, rosiglitazone, pioglitazone, ciglitazone or pharmaceutically acceptable salts, isomers or derivatives thereof.
22. (original) The dosage form of claim 21 wherein said controlled release core is an osmotic tablet.
23. (currently amended) The dosage form of claim 22 wherein the osmotic tablet consists essentially of:

- (a) a core consisting essentially of :
 - (i) 50-98% of said metformin or a pharmaceutically acceptable salt thereof biguanide drug;
 - (ii) 0.1-40% of a binding agent;
 - (iii) 0-20% of an absorption enhancer; and
 - (iv) 0-5% of a lubricant;
- (b) optionally a secondary seal coat surrounding the core; and
- (c) a semipermeable membrane consisting essentially of:
 - (i) 50-99% of a polymer;
 - (ii) 0-40% of a flux enhancer; and
 - (iii) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the metformin or a pharmaceutically acceptable salt thereof biguanide drug.

- 24. (currently amended) The dosage form of claim 21 wherein said metformin or a pharmaceutically acceptable salt thereof biguanide is metformin hydrochloride and the thiazolidinedione derivative is pioglitazone hydrochloride.
- 25. (canceled).
- 26. (canceled).
- 27. (currently amended) The dosage form of claim 21 wherein the release of the biguanide drug metformin or a pharmaceutically acceptable salt thereof is not regulated by an expanding polymer.
- 28. (currently amended) The dosage form of claim 21 wherein said controlled release of said biguanide drug metformin or a pharmaceutically acceptable salt thereof provides a Tmax of 8-12 hours.
- 29. (original) The dosage form of claim 21 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-12 hours.
- 30. (original) The dosage form of claim 29 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-4 hours.
- 31. (currently amended) A pharmaceutical dosage form having a first and second active drug, said dosage form consisting essentially of:

- (a) an osmotic tablet core wherein ~~a~~ the osmotic tablet core consists essentially of:
- (i) a core consisting essentially of:
 - (I) 50-98% of metformin or a pharmaceutically acceptable salt thereof;
 - (II) 0.1-40% of a binding agent; and
 - (III) 0-20% of an absorption enhancer;
 - (ii) optionally a secondary seal coat surrounding the core; and
 - (iii) a semipermeable membrane consisting essentially of:
 - (I) 50-99% of a polymer;
 - (II) 0-40% of a flux enhancer and
 - (III) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the metformin;
- (b) a primary seal coat that does not contain an active pharmaceutical ingredient, that rapidly disperses or dissolves in water and that is applied to the osmotic tablet core
- (c) an immediate release thiazolidinedione derivative containing coating coat consisting essentially of :
- (i) ~~a thiazolidinedione derivative selected from the group consisting of troglitazone, rosiglitazone, pioglitazone, eigitazone or pharmaceutically acceptable salts, isomers or derivatives thereof [.]~~; and
 - (ii) a binder

wherein the immediate release coating coat is applied to the primary seal coat that is applied to the osmotic tablet core using a solvent mixture comprising water and an organic solvent and wherein the dosage form provides a Tmax of 8-12 hours for the metformin and a Tmax of 1-4 hours for the pioglitazone thiazolidinedione derivative.